K122168

SpineSmith Cynch Spinal System – VisuALIF Interbody Fusion Implant System

510(k) Summary of Safety and Effectiveness

OCT 11 2012

SUBMITTED BY	SpineSmith Partners, LP 93 Red River Austin, TX 78701
ESTABLISHMENT REGISTRATION NUMBER	3006404071
CONTACT PERSON	**Clifton (Chris) Naivar** Director – Quality and Regulatory Affairs Phone: 512-637-2068 Fax: 512-637-2096 Email: cnaivar@spinesmithusa.com
SUBMISSION PREPARED BY	**Clifton (Chris) Naivar** Director – Quality and Regulatory Affairs Phone: 512-637-2068
DATE PREPARED	October 10, 2012
CLASSIFICATION	OVD 888.3080- Intervertebral Fusion Device with Bone Graft, Lumbar
COMMON NAME	Intervertebral Body Fusion Device
PROPRIETARY NAME	SpineSmith Cynch Spinal System – VisuALIF Challenging Access Interbody Fusion Implant System

IDENTIFICATION OF PREDICATE DEVICES:
The SpineSmith VisuALIF Challenging Access System was determined to be substantially equivalent to the previously cleared VisuALIF System (K102090, SpineSmith; Cleared 09/09/2010).

DEVICE DESCRIPTION:
The VisuALIF Challenging Access System an extension to the VisuALIF System and both are part of the Cynch Spinal System. It is available in various sizes to accommodate individual patient anatomy. The VisuALIF Challenging Access implant is a lumbar intervertebral body fusion device that is intended to be implanted singularly via an open anterior approach. VisuALIF Challenging Access is intended to be used with the two (2) or more bone screws provided with the accompanying anterior cover plate assembly.

Addition of additional screw holes and positions to the existing VisuALIF System is intended to provide surgeons with additional surgical approach options. There are no changes with respect to indications or intended use as compared to the VisuALIF Spinal System cleared previously via K102090.

INDICATIONS:
The VisuALIF System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment.The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with autograft to facilitate fusion.

The VisuALIF is a stand-alone device intended to be used with an anterior cover plate and a minimum of two provided bone screws angled both cephalad and caudal with a minimum of one screw into each vertebral body. Should the physician choose to use fewer than the two screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:
The purpose of this submission is to add the VisuALIF Challenging Access device, which may be implanted via an open anterior approach. The Cynch System implants are manufactured from PEEK Optima LT1 and contain three (3) radiopaque tantalum markers to assist the surgeon with proper placement of the device. The subject device (VisuALIF Challenging Access – ALIF device) has similar technological characteristics as the predicate devices identified above (SpineSmith's Cynch System per K102090). Specifically, the following characteristics support this conclusion:

- Intended for stand-alone use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis.
- 'U' shaped implant design to allow for placement of autograft bone
- Implant material: PEEK Optima LT1 per ASTM F2026 with radiopaque tantalum marker bar per ASTM F-560-05, and Titanium alloy screws/cover plate assembly per ASTM F-136
- Substantially equivalent results of non-clinical testing relative to static and dynamic testing (per ASTM F2077-03), subsidence (per ASTM F2267-04), and expulsion (per ASTM Draft Standard F-04.25.02.02)

DISCUSSION OF NON-CLINICAL TESTING:

The following non-clinical tests were conducted:

- Static and dynamic compression testing, conducted in accordance with ASTM F2077-03
- Static and dynamic compression-shear testing, conducted in accordance with ASTM F2077-03
- Subsidence testing, conducted in accordance with ASTM F2267-04
- Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02

CONCLUSIONS:

The subject and predicate device share the same intended use, primary implant design and material of manufacture. The non-clinical mechanical test results demonstrate that any minor differences do not impact device performance as compared to the predicates and demonstrate that the VisuALIF Challenging Access System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 11 2012

Spine Smith Partners, LLC
% Mr. Clifton (Chris) Naviar
Director, Quality and Regulatory Affairs
93 Red River
Austin, Texas 78701

Re: K122168
Trade/Device Name: SpineSmith Cynch Spinal System – VisuALIF Challenging Access Plate Interbody Fusion Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: September 12, 2012
Received: September 14, 2012

Dear Mr. Naviar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): **K122168**

Device Name: **SpineSmith Cynch Spinal System – VisuALIF Challenging Access Plate Interbody Fusion Implant System**

Indications for Use:

The VisuALIF System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment.The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with autograft to facilitate fusion.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122168